

Please add new claim 45 as follows.

Sub 56

--Claim 45. Isolated nucleic acid of claim 2 wherein the nucleic acid is purified.--

REMARKS

Claim 1-44 are pending in the present application. Claims 8-25 and 27-44 have been withdrawn from consideration. Claims 1-7 and 26 stand rejected. Claims 1 and 3 have been canceled. Claim 2, 4-7 and 26 have been amended. New claim 45 has been added. Support for the isolated and purified nucleic acid of new claim 45 can be found throughout the specification, for example pages 20 to 23 (i.e., Example 1) of the specification. No new matter has been added. Applicant respectfully requests reconsideration and withdrawal of all objections and rejections.

Objection Under 37 CFR 1.84

The Office Action states that formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Applicant respectfully requests that this objection be held in abeyance until allowance of the claims. Substitute drawings will be submitted upon allowance of the claims.

Objection to Claim 26

The Office Action states that claim 26 is objected to for being dependent upon non-elected claims. Claim 26 has been amended to be dependent on elected claims 2, 4, 6 or 7.

Rejection Under 35 U.S.C. § 101

The Office Action states the claims 1-4 and 6 are rejected as being directed to naturally occurring products of nature and thus non-statutory subject matter. Applicant respectfully disagrees. The specification makes it clear that the present invention is directed to statutory subject matter. For example, the specification on page 3 (first full paragraph) to page 5 (second full paragraph) states that tumour-infiltrating lymphocytes (TIL) isolated from a kidney carcinoma were used to obtain nucleotide sequences. The specification on page 5 (third full paragraph) to page 6 (first full paragraph) also states that sequences were obtained via amplification and reverse transcriptase of RNA isolated from the tumour. Such isolated nucleic acids cannot be considered naturally occurring products of nature.

Nevertheless, claim 2 has been amended to more clearly describe the present invention. In particular, claim 2 as amended to recite "isolated" nucleic acid. The amendment of claim 2 makes it clear that the present invention is directed to nucleic acids, vectors and cells wherein the nucleic acid has been isolated. Accordingly, the nucleic acids, vectors and cells of the present invention are not directed to naturally occurring products of nature. As discussed above, the amendment is fully supported by the specification. Applicant thus urges that the present invention is directed to statutory subject matter.

Rejections Under 35 U.S.C. § 112, first paragraph

The Office Action states that several claims are rejected as not enabled. The Office Actions states that claims 1-2 and 26 are rejected because the disclosure is insufficient to

enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. In particular, the Office Action states that claims 1-7 and 26 are rejected as not enabled because the specification does not reasonably provide enablement for the broader recitation of any "functional derivative" or any "fragment thereof." Applicant respectfully disagrees that these claims are not enabled for the phrase "functional derivative." This phrase is clearly enabled by the specification. For example, the specification (last paragraph) on page 10 refers describes the preparation of "functional derivatives" by means of recombinant DNA techniques. The specification on page 11 (first paragraph) describes preferred "functional derivatives" of T cell receptor chains or T cell receptors as single chain T cell receptors composed of the variable domains of the α and β chain and a constant domain, as well as the preparation of such "functional derivatives."

Nevertheless, claim 1 has been canceled and claim 2 amended to more clearly describe the invention. Claim 2 has been amended to recite the amino acid sequences of claim 4 and canceled claim 3. Applicant notes the admission on page 3 of the Office Action that the specification is enabling for a nucleic acid which codes for an α chain of the human T cell receptor comprising SEQ ID NO: 23 where $X_1 \dots X_n$ is one of the amino acid sequences recited in claims 3 and 4, a Fab, a single chain antibody, a soluble TCR fragment or composition thereof. Applicant accordingly urges that one skilled in the art would understand how to make and use the isolated nucleic acid of the present invention which codes for the α chain of a human T cell receptor, or for a functional derivative or a fragment thereof and comprises a CDR3 region having a nucleotide sequence coding for the recited amino acid sequence which includes an amino acid sequence selected from the group of amended claim 2.

The Office Action states that claims 1-2, 5-7 and 26 are not enabled because it would require undue experimentation for one skilled in the art to practice the claimed invention. In particular, the Office Action states that the specification does not reasonably provide enablement where X is any amino acid or for a nucleic acid which codes for any TCR alpha chain comprising a CDR3 region formed from a combination of a Va20 and Ja22 gene segment. As discussed above, claim 2 has been amended to recite the amino acid sequences of claim 4 and canceled claim 3. Applicant notes the admission on pages 4 and 5 of the Office Action that the specification is enabling for a nucleic acid that codes for a human T cell receptor comprising SEQ ID NO: 23 where X₁ . . . X_n is one of the amino acid sequences recited in claims 3 and 4, a Fab, a single chain antibody, a soluble TCR fragment or composition thereof. Applicant accordingly urges that claims are enabled.

Finally, the Office Action states that claims 2-7 are not enabled because it would require undue experimentation for one skilled in the art to practice the invention. In particular, the Office Action states that the specification does not reasonably provide enablement for a nucleic acid which comprises a nucleotide sequence that encodes a polypeptide with at least 80% identity to SEQ ID NO: 23. Claim 2 has been amended. Claim 2 has been amended not to require a nucleotide sequence which codes for an amino acid sequence which is at least 80% identical with the amino acid sequence of SEQ ID NO: 23. Applicant urges that this rejection is obviated.

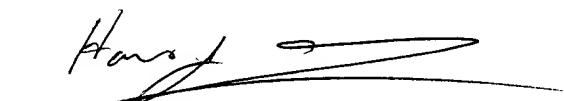
Rejections Under 35 U.S.C. § 112, second paragraph

The Office Action states that claims 2-7 and 26 are rejected as indefinite. In particular, the Office Action states that it is unclear what is meant by the phrase "equivalent

recognition specificity". Claim 2 has been amended to more clearly define the present invention. Claim 2 has been amended to indicate that the phrase "equivalent recognition specificity" means recognition specificity as achieved with a T cell receptor comprising a CDR3 region with the amino acid sequence of SEQ ID NO: 23. Such amendment is fully supported throughout the specification. Applicant urges that the phrase "equivalent recognition specificity" is not indefinite.

Applicant respectfully urges that claims 2, 4-7, 26 and 45 are in condition for allowance, and accordingly, respectfully requests an early notice of allowance. In the event this paper is not considered to be timely filed, Applicant respectfully petitions for an appropriate extension of time. Any fees for such extension, together with any additional fees which may be due with respect to this paper, may be charged to our Deposit Account No. 01-2300.

Respectfully submitted,
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